



ENCELTO™
(revakinagene taroretcel-lwey)
implant, for intravitreal use

Product Acquisition Channels

Billing and Coding

ASC Billing Considerations

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BILLING AND CODING GUIDE

for Ambulatory Surgery Centers (ASCs) and Hospital Outpatient Departments (HOPDs)

This guide is intended to be an educational reference and for informational purposes only. It is not intended to provide medical, legal, or reimbursement advice.

Each healthcare professional and provider is responsible for determining appropriate codes, coverage, reimbursement, and payment for individual patients.

Coding, coverage, and reimbursement policies vary by payer and are subject to change, and may not be current when you view them. Please review and verify individual payer policies for details regarding specific requirements for ENCELTO for individual patients. All codes reported on the claim form must be supported by medical record documentation, as required by the payer.

Providing this information does not represent a guarantee of coverage, coverage levels, reimbursement, or payment for ENCELTO. All such decisions are made by individual payers.

Please see Important Safety Information on pages 13-14 and accompanying full [Prescribing Information](#).



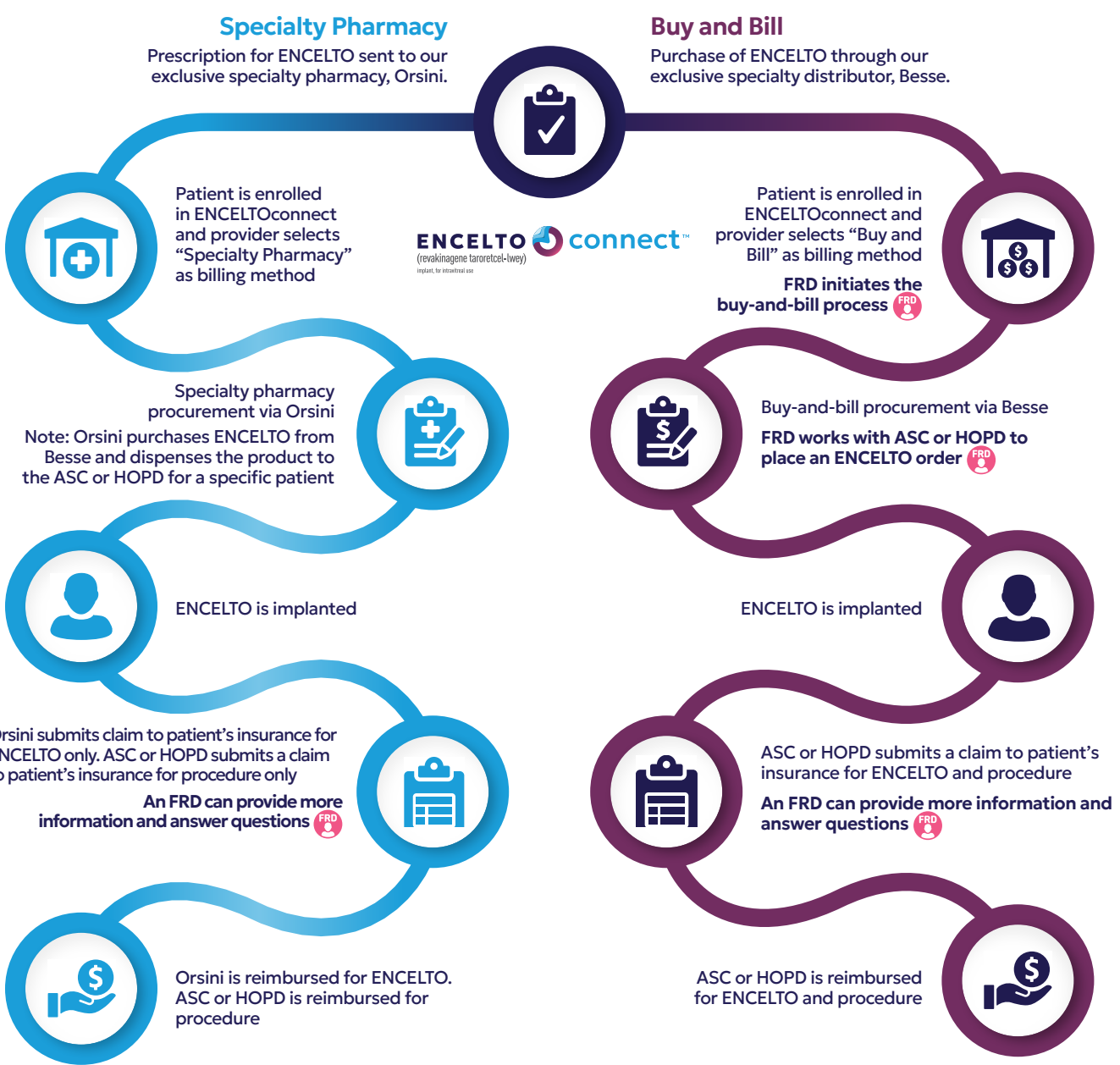
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Product Acquisition Channels

ENCELTO can be acquired 1 of 2 ways, depending on the logistical and operational needs of the ASC or HOPD, and the patient’s insurance requirements. The chosen pathway determines who is purchasing and submitting a claim for the cost of ENCELTO.



Field Reimbursement Director (FRD)

Please see Important Safety Information on pages 13-14 and accompanying full [Prescribing Information](#).



Billing and Coding

This section provides general coding and appropriate use information for ENCELTO when implanted by a healthcare provider in an ASC or an HOPD.

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Codes¹

ICD-10-CM codes are used to identify a patient's diagnosis and support the medical necessity of treatment. The following codes may be appropriate to describe idiopathic macular telangiectasia type 2 (MacTel):

ICD-10-CM Code	Description
H35.071	Retinal telangiectasis, right eye
H35.072	Retinal telangiectasis, left eye
H35.073	Retinal telangiectasis, bilateral
H35.079 ^a	Retinal telangiectasis, unspecified eye

^a Check payer policies for coding requirements when billing with unspecified ICD-10-CM codes.

National Drug Codes (NDCs)^{2,3}

An NDC code is a unique 10-digit number that serves as a universal product identifier for drugs. Payers generally require healthcare providers to report the Health Insurance Portability and Accountability Act compliant 11-digit NDC on claims.

Payers may also require a unit of measure (UOM) qualifier and quantity. For ENCELTO, the UOM qualifier is UN (unit) and its quantity is 1. Check individual payer policies for reporting the NDC and UOM on claims.

10-Digit NDC	11-Digit NDC	Description
82958-501-01	82958-0501-01	Single-dose implant that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line)

NDC and UOM

N482958050101 UN1

Healthcare Common Procedure Coding System (HCPCS) Codes⁴

HCPCS codes are used to report drugs and other procedures. For dates of service on or after October 1, 2025, ENCELTO may be reported with its product-specific HCPCS code.

HCPCS Code	Description
J3403 ^a	Revakinagene taroretcel-lwey, per implant

^a ASCs and HOPDs will be reimbursed separately for ENCELTO when it is acquired under the buy-and-bill pathway.

HCPCS Modifier⁴

Modifiers provide payers with additional information regarding services rendered. The following HCPCS modifier may be applicable for ENCELTO:

Modifier ^a	Description	Appropriate Use
JZ	Zero drug amount discarded/not administered to any patient	Report modifier JZ with J3403 to show that there was no drug wastage (required on Medicare claims, check other payer requirements)
TB	Drug or biological acquired with the 340B Drug Pricing Program discount, reported for informational purposes	Report modifier TB with J3403 when ENCELTO is acquired through the 340B Drug Pricing Program (required for 340B covered entities claims)

^a See ASC Billing Considerations section for additional modifiers that may be applicable for ASC claims with dates of service on or after October 1, 2025.

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Billing and Coding (cont'd)

Current Procedural Terminology (CPT®) Code⁵

CPT codes describe procedures and services performed by healthcare providers. ENCELTO is intended for surgical intravitreal implantation under sterile technique by a qualified ophthalmologist. The following CPT code may be appropriate to report the intravitreal implantation:

CPT Code	Description
67027	Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous

CPT Modifiers⁶

The following modifiers may be appropriate to indicate the laterality of the intravitreal implantation:

Modifier	Description
RT	Right side (used to identify procedures performed on the right side of the body)
LT	Left side (used to identify procedures performed on the left side of the body)

Place of Service Codes⁸

Place of service (POS) codes are 2-digit codes used to indicate the setting in which the service was provided for professional claims. The following POS code may be appropriate when the intravitreal implantation of ENCELTO is performed in an ASC:

POS Code	POS Name	Description
24	Ambulatory surgical center	A freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis

Revenue Codes⁸

Revenue codes are used to identify the ASC or HOPD department in which services were provided, the types of services provided, and the supplies used on the CMS-1450 claim form. The revenue codes below may be used to report ENCELTO and the intravitreal implantation.

Service	Revenue Code	Description
ENCELTO	0636	Drugs requiring detailed coding
Intravitreal implantation ^a	0361	Operating room services, minor surgery

^a Other revenue codes may apply.

Please see Important Safety Information on pages 13-14 and accompanying full [Prescribing Information](#).



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ASC Billing Considerations for ENCELTO⁹

Information applicable for ASCs that bill using the CMS-1500 claim form

Professional services such as ENCELTO therapy are billed on the CMS-1500 (837P) claim form. The charge field character limitations require multiple claims to report the charge for one ENCELTO implant.

The CMS-1500 charge fields (Items 24F and 28) for dollar amounts have a 7-character limitation; therefore, the highest dollar value allowed per line and on one claim form is \$99,999.99. Multiple claims may be submitted with billing units and charges split any number of ways so long as the charge on any one claim form line (Item 24F) or total per claim (Item 28) does not exceed \$99,999.99. **Avoid same dollar amounts on the multiple claims to avoid delays/denials for duplicate claims.**

CMS has specific claim submission requirements for Medicare ENCELTO claims in the ASC with dates of service on or after October 1, 2025. These requirements involve submitting multiple claims with specific modifiers to communicate to the Medicare Administrative Contractor (MAC) that the billing unit per ENCELTO implant has been fractionated or divided for claims processing purposes.¹⁰

ASC Modifiers for ENCELTO Billing^{9,10}

Split claim and modifier guidance varies by payer and should be verified prior to submitting a split claim.

Modifier	Description	Appropriate Use
JZ	Zero drug amount discarded/not administered to any patient	Attach to J3403 on each ENCELTO claim to indicate there was no drug wastage Required by Medicare; check other payer reporting requirements
LU	Fractionated payment	Attach to J3403 on each ENCELTO claim to indicate fractionated payment for fractionated billing units Required by Medicare; check other payer reporting requirements
76	Repeat service or payment by the same physician or other qualified healthcare professional	Attach to J3403 on each subsequent claim for ENCELTO, (eg, it is not used on the first claim) Required by Medicare; check other payer reporting requirements
59	Distinct procedural service	Attach to J3403 on each subsequent claim for ENCELTO, (eg, it is not used on the first claim) per payer-specific guidance Not required by Medicare; check other payer reporting requirements

For J3403, the total billing units should not exceed “1” billing unit across all submitted claims. A different number of fractionated units may need to be billed to avoid denials for duplicate claims. Medicare does not require NDC reporting on claims. Check payer requirements and format for reporting NDC, UOM, and NDC quantity on fractionated claims.

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ASC Other Payer Sample CMS-1500 Claim Form

Information applicable for ASCs that bill using the CMS-1500 claim form

Sample CMS-1500 Claim Form or Electronic Equivalent for Buy and Bill

CMS-1500 Claim 1¹¹

Item Number 19 Additional Claim Information: Use this field to indicate which claim in the series is being submitted

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Claim 1 of X: Dollar amount exceeds charge line amount for ENCELTO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) ICD Ind.

A: H35.07x B: _____ C: _____ D: _____
E: _____ F: _____ G: _____ H: _____
I: _____ J: _____ K: _____ L: _____

Item Number 21 Diagnosis: Enter the appropriate diagnosis code; eg,
• ICD-10-CM: H35.07x (Retinal telangiectasis)
Note: The “x” indicates that an additional character is required to complete the valid code. Final code depends on medical record documentation

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)			E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSDT (Signify Pln)	I. ID. QUAL	J. RENDERING PROVIDER ID. #	K. OTHER INFORMATION
From	To						CPT/HCPCS	MODIFIER									
MM	DD	YY	MM	DD	YY												
N482958050101 UNxx																	
MM	DD	YY	MM	DD	YY	24		J3403	JZ		A	XXXX	XX		NPI		
MM	DD	YY	MM	DD	YY	24		67027	XX		A	XXXX	XX	1	NPI		

Item Number 24A Date(s) of Service:
Enter the NDC and UOM in the shaded area above the month, day, and year. The “N4” qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UOM qualifier and NDC quantity
Note: Check payer requirements and format for reporting NDC, UOM, and NDC quantity

Item Number 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
• **Drug:** J3403 for ENCELTO
• **Drug Modifier:** JZ to show there was no drug wastage
• **Administration:** 67027 for intravitreal implantation
• **Procedure Modifier:** Add modifier LT or RT to indicate the laterality of the implantation
Note: Report additional modifiers as appropriate

Item Number 24G Units: Enter the appropriate number of billing units for each line item

CMS-1500 Subsequent Claims¹¹

Item Number 19 Additional Claim Information: Use this field to indicate which claim in the series is being submitted

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Claim 2 of X: Dollar amount in claim 1 exceeds charge line amount for ENCELTO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) ICD Ind.

A: H35.07x B: _____ C: _____ D: _____
E: _____ F: _____ G: _____ H: _____
I: _____ J: _____ K: _____ L: _____

Item Number 21 Diagnosis: Enter the appropriate diagnosis code; eg,
• ICD-10-CM: H35.07x (Retinal telangiectasis)
Note: The “x” indicates that an additional character is required to complete the valid code. Final code depends on medical record documentation

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)			E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSDT (Signify Pln)	I. ID. QUAL	J. RENDERING PROVIDER ID. #	K. OTHER INFORMATION
From	To						CPT/HCPCS	MODIFIER									
MM	DD	YY	MM	DD	YY												
N482958050101 UNxx																	
MM	DD	YY	MM	DD	YY	24		J3403	JZ	xx	A	XXXXX	XX		NPI		
MM	DD	YY	MM	DD	YY	24		67027	xx		A	XXXXX	XX	0	NPI		

Item Number 24A Date(s) of Service:
Enter the NDC and UOM in the shaded area above the month, day, and year. The “N4” qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UOM qualifier and NDC quantity
Note: Check payer requirements and format for reporting NDC, UOM, and NDC quantity

Item Number 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
• **Drug:** J3403 for ENCELTO
• **Drug Modifier:** JZ and additional modifier per payer reporting requirements
• **Administration:** 67027 for intravitreal implantation
• **Procedure Modifier:** Add modifier LT or RT to indicate the laterality of the implantation
Note: Report additional modifiers as appropriate

Item Number 24G Units: Enter the appropriate number of billing units for each line item

ASC Medicare Sample CMS-1500 Claim Form

Information applicable for ASCs that bill using the CMS-1500 claim form

Sample CMS-1500 Claim Form or Electronic Equivalent for Buy and Bill

CMS-1500 Claim 1¹¹

Item Number 19 Additional Claim Information: Use this field to indicate which claim in the series is being submitted

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Claim 1 of X: Dollar amount exceeds charge line amount for ENCELTO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) ICD-10-Code

A: H35.07x B: _____ C: _____ D: _____
E: _____ F: _____ G: _____ H: _____
I: _____ J: _____ K: _____ L: _____

Item Number 21 Diagnosis: Enter the appropriate diagnosis code; eg,
• ICD-10-CM: H35.07x (Retinal telangiectasis)
Note: The “x” indicates that an additional character is required to complete the valid code. Final code depends on medical record documentation

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE		C. EMG			D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER				E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSDT (Signify Pln)	I. ID. QUAL	J. RENDERING PROVIDER ID. #	K. ER INFORMATION
From	To																				
MM	DD	YY	MM	DD	YY																
N482958050101 UNxx																					
MM	DD	YY	MM	DD	YY	24					J3403	JZ	LU		A	XXXXX	XX	XX		NPI	
MM	DD	YY	MM	DD	YY	24					67027	XX			A	XXXXX	XX	1		NPI	

Item Number 24A Date(s) of Service:
Enter the NDC and UOM in the shaded area above the month, day, and year. The “N4” qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UOM qualifier and NDC quantity
Note: Check payer requirements and format for reporting NDC, UOM, and NDC quantity

Item Number 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
• **Drug:** J3403 for ENCELTO
• **Drug Modifier:** JZ and LU to align with CMS requirements
• **Administration:** 67027 for intravitreal implantation
• **Procedure Modifier:** Add modifier LT or RT to indicate the laterality of the implantation
Note: Report additional modifiers as appropriate

Item Number 24G Units: Enter the appropriate number of billing units for each line item

CMS-1500 Subsequent Claims¹¹

Item Number 19 Additional Claim Information: Use this field to indicate which claim in the series is being submitted

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Claim 2 of X: Dollar amount in claim 1 exceeds charge line amount for ENCELTO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) ICD-10-Code

A: H35.07x B: _____ C: _____ D: _____
E: _____ F: _____ G: _____ H: _____
I: _____ J: _____ K: _____ L: _____

Item Number 21 Diagnosis: Enter the appropriate diagnosis code; eg,
• ICD-10-CM: H35.07x (Retinal telangiectasis)
Note: The “x” indicates that an additional character is required to complete the valid code. Final code depends on medical record documentation

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE		C. EMG			D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER				E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSDT (Signify Pln)	I. ID. QUAL	J. RENDERING PROVIDER ID. #	K. ER INFORMATION
From	To																				
MM	DD	YY	MM	DD	YY																
N482958050101 UNxx																					
MM	DD	YY	MM	DD	YY	24					J3403	JZ	LU	76	A	XXXXX	XX	XX		NPI	
MM	DD	YY	MM	DD	YY	24					67027	XX			A	XXXXX	XX	0		NPI	

Item Number 24A Date(s) of Service:
Enter the NDC and UOM in the shaded area above the month, day, and year. The “N4” qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UOM qualifier and NDC quantity
Note: Check payer requirements and format for reporting NDC, UOM, and NDC quantity

Item Number 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
• **Drug:** J3403 for ENCELTO
• **Drug Modifier:** JZ, LU, and 76 to align with CMS requirements
• **Administration:** 67027 for intravitreal implantation
• **Procedure Modifier:** Add modifier LT or RT to indicate the laterality of the implantation
Note: Report additional modifiers as appropriate

Item Number 24G Units: Enter the appropriate number of billing units for each line item

ASC Medicare Sample CMS-1500 Claim Form

Sample CMS-1500 Claim Form or Electronic Equivalent for Specialty Pharmacy Acquisition^{11,12}

Providers who obtained ENCELTO through the specialty pharmacy will bill only for the intravitreal implantation. However, some payers may require the drug information be included on the claim form to process the claim. Please check with the individual payer for billing requirements.

The following is an example of how a physician's services may be billed using a CMS-1500 claim form and is for illustrative purposes only. It is always the provider's responsibility to submit true and accurate claims for the products and services rendered.

Item 21 Diagnosis: Enter the appropriate diagnosis code; eg,

- ICD-10-CM: H35.07x (Retinal telangiectasis)

Note: The "x" indicates that an additional character is required to complete the valid code

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. H35.07x	B. _____	C. _____	D. _____
E. _____	F. _____	G. _____	H. _____
I. _____	J. _____	K. _____	L. _____

24. A. DATE(S) OF SERVICE							B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)		E. DIAGNOSIS POINTER	F. CHARGES	G. DAYS OR UNITS
From	To												
MM	DD	YY	MM	DD	YY	24							
1	MM	DD	YY	MM	DD	YY	24	J3403	JZ	A	0.00	0	
2	MM	DD	YY	MM	DD	YY	24	67027	xx	A	XXXXX	XX 1	

Item 24D Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,

- **Drug:** J3403 for ENCELTO
- **Modifier:** JZ to show that no product was wasted
- **Administration:** 67027 for intravitreal implantation
- **Procedure Modifier:** Add modifier LT or RT to indicate the laterality of the implantation

Note: Add additional modifiers as appropriate

Item 24E Diagnosis Pointer: Enter the appropriate letter (A-L) that corresponds to the diagnosis in Item 21

Item 24F Charges: Check payer-specific guidance for reporting zero charge for drugs

Please see Important Safety Information on pages 13-14 and accompanying full [Prescribing Information](#).





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HOPD Sample CMS-1450 Claim Form

Information applicable for ASCs and HOPDs that bill using the CMS-1450 claim form

Sample CMS-1450 Claim Form or Electronic Equivalent for Buy and Bill

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES
0636	N482958050101 UN1 ENCELTO	J3403 JZ	MMDDYY	1	xxx.xx
0361	Intravitreal implantation	67027 xx	MMDDYY	1	xxx.xx

50	51	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	57 OTHER PRV ID
CREATION DATE				TOTALS			

58 INSURED'S NAME	61 GROUP NAME	62 INSURANCE

63 TREATMENT AUTHORIZATION CODE	65 EMPLOYER NAME
H35.07x	

FL 42 Revenue Code: Enter the appropriate revenue code; eg,
 • 0636 for ENCELTO
 • 0361 for intravitreal implantation
Note: Other revenue codes may apply

FL 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
 • **Drug:** J3403 for ENCELTO
 • **Modifier:** JZ indicates that no product was wasted
 • **Administration:** 67027 is used for intravitreal implantation
 • **Procedure Modifier:** Add modifier LT or RT to indicate the laterality of the implantation
Note: Report additional modifiers as appropriate

FL 46 Units of Service: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
 • For J3403, 1 billing unit is reported

FL 43 Revenue Description: Enter the NDC, UOM, and NDC quantity in the shaded area above the month, day, and year. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UOM qualifier and quantity
Note: Check payer requirements and format for reporting NDC, UOM, and NDC quantity

FL 67 Principal Diagnosis Code and 67A-67Q Other Diagnosis Codes: Enter the appropriate diagnosis code; eg,
 • ICD-10-CM: H35.07x (Retinal telangiectasis)
Note: The "x" indicates that an additional character is required to complete the valid code. Final code depends on medical record documentation

ASC and HOPD Claims Submission Checklist

Billing and coding will vary based on payer-specific requirements. It is important to confirm payer-specific requirements prior to claim submission in order to avoid processing delays or denials.

- Confirm** that the diagnosis code is accurate and supports the medical necessity of ENCELTO
 - Be sure to code to the **highest level of specificity** to avoid claim denials. Ensure the laterality of the diagnosis code matches the modifier laterality on CPT 67027
 - Be sure to bill using the ENCELTO-specific HCPCS code J3403 for dates of service on and after October 1, 2025
- Use the appropriate 11-digit NDC, UOM, and NDC quantity** to match the units billed per claim line. Please check payer-specific requirements.
- Check payer-specific split billing requirements** if total charges exceed the 7-character limitation on the CMS-1500 form
- Append appropriate medical record documentation**, such as clinical information, imaging, and/or a letter of medical necessity
- Provide prior authorization (PA) number in Item 23 of the claim form as appropriate**
- Ensure **accuracy and completeness** of the **patient's information** (eg, date of birth, insurance identification number) and **provider's information** (eg, National Provider Identifier [NPI])



Reach out to your dedicated Neurotech Field Reimbursement Director (FRD), who may be able to provide certain coverage and on-label coding information. Discussions with your FRD do not replace the need to verify all information submitted for an individual patient with the payer.

Please see Important Safety Information on pages 13-14 and accompanying full [Prescribing Information](#).

FRD Support



Your FRD is available to provide support through the coverage process



General and/or plan-specific reimbursement education, including:

- Billing and coding
- PA requirements and processes
- Appeals and denials resolution



Information about Neurotech's reimbursement-related resources and programs, such as the co-pay assistance through ENCELTOconnect



Providing appropriate assistance with questions on patient coverage, access and reimbursement



Resources such as letter of medical necessity and prior authorization appeals sample letters



If you or your patients have questions about insurance coverage, reimbursement, or billing, ENCELTOconnect can help. For more information or assistance, please call ENCELTOconnect at 1-877-ENCELTO (1-877-362-3586) or visit [ENCELTO.com/ecp/access-and-resources](https://www.enceyto.com/ecp/access-and-resources).

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

ENCELTO is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENCELTO is contraindicated in patients with active or suspected ocular or periocular infections, and in patients with known hypersensitivity to Endothelial Serum Free Media (Endo-SFM).

WARNINGS AND PRECAUTIONS

ENCELTO implantation surgery and/or implantation related procedures have been associated with the following:

Severe Vision Loss

Severe vision loss defined as three or more lines of visual acuity loss [≥ 15 Early Treatment Diabetic Retinopathy Study (ETDRS) letters] has occurred following ENCELTO implantation. Monitor patients for signs and symptoms of vision loss and manage as clinically indicated.

Infectious Endophthalmitis

Infectious endophthalmitis may occur following ENCELTO implantation. Signs and symptoms of infectious endophthalmitis include progressively worsening eye pain, vision loss, or scleral and conjunctival injection. To mitigate the risk of endophthalmitis, use proper aseptic surgical technique for ENCELTO implantation. Monitor patients for signs or symptoms of infectious endophthalmitis. Remove ENCELTO implant if infectious endophthalmitis occurs and manage symptoms according to clinical practice.

Retinal Tear and Detachment

Retinal tears and retinal detachment may occur following ENCELTO implantation. Signs and symptoms of retinal tears include acute onset of flashing lights, floaters, and/or loss of visual acuity. Signs and symptoms of retinal detachment may include progressive visual field loss and/or loss of visual acuity. Use standard vitreoretinal surgical techniques during ENCELTO implantation to minimize the risk of retinal tears and retinal detachment. Monitor for any signs or symptoms of retinal tear and/or retinal detachment. Treat rhegmatogenous retinal detachment and retinal tears promptly. Remove ENCELTO implant, if vitrectomy with a complete gas fill or silicone oil fill is required.

Vitreous Hemorrhage

Vitreous hemorrhage, which may result in temporary vision loss, has occurred following ENCELTO implantation. Patients receiving antithrombotic medication (eg, oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs) may be at increased risk of vitreous hemorrhage. To reduce the risk of vitreous hemorrhage, interrupt antithrombotic medications prior to the ENCELTO implantation. Vitrectomy surgery may be necessary to clear severe, recurrent, or non-clearing vitreous hemorrhage. If the patient has a late onset vitreous hemorrhage (greater than one year following ENCELTO implantation surgery), examine the ENCELTO implantation site for possible implant extrusion. If implant extrusion has occurred, surgically reposition ENCELTO.

Implant Extrusion

Implant extrusion through the initial scleral wound has occurred following ENCELTO implantation. Signs and symptoms of implant extrusion include recurrent uveitis, vitreous hemorrhage, eye pain more than one year after implantation, or visibility of titanium fixation loop under the conjunctiva. To reduce the risk of implant extrusion, carefully follow the specific surgical steps for ENCELTO implantation.

Evaluate patients after 6 months to confirm proper positioning of ENCELTO and then annually. If ENCELTO begins to extrude, surgically reposition ENCELTO to a proper scleral wound depth either in the same site or in the opposing inferior quadrant of the vitreous cavity.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Cataract Formation

Cataract formation, including cataract cortical, cataract nuclear, cataract subcapsular, cataract traumatic, and lenticular opacities, has occurred following ENCELTO implantation. To reduce the risk of ENCELTO-related cataract formation or progression, carefully follow the specific surgical steps for ENCELTO implantation.

Suture Related Complications

Suture related complications, including conjunctival erosions due to suture tips and suture knots, have occurred following ENCELTO implantation.

To mitigate the risk of suture related complications, carefully follow the specific surgical steps for ENCELTO implantation and manage suture-related complications as clinically indicated.

Delayed Dark Adaptation

Delayed Dark Adaptation, a delay in the ability to adjust vision from a bright lighting condition to a dim lighting, has occurred following ENCELTO administration which remained unchanged for the duration of study follow up. Advise patients to take caution while driving and navigating in the dark.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 2\%$) reported with ENCELTO were conjunctival hemorrhage, delayed dark adaptation, foreign body sensation, eye pain, suture related complications, miosis, conjunctival hyperemia, eye pruritus, ocular discomfort, vitreous hemorrhage, blurred vision, headache, dry eye, eye irritation, cataract progression or formation, vitreous floaters, severe vision loss, eye discharge, anterior chamber cell, iridocyclitis.

Please see accompanying full [Prescribing Information](#).

References: 1. Centers for Medicare & Medicaid Services. 2026 ICD-10-CM. Accessed September 25, 2025. <https://www.cms.gov/medicare/coding-billing/icd-10-codes> 2. Food and Drug Administration. Format of the national drug code. Accessed September 25, 2025. <https://www.fda.gov/media/173715/download> 3. ENCELTO. Prescribing Information. Neurotech Pharmaceuticals, Inc. 4. Centers for Medicare & Medicaid Services. October 2025 alpha-numeric HCPCS file. Accessed September 18, 2025. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update> 5. American Medical Association. CPT 2025. Professional Edition. AMA; 2024. 6. Centers for Medicare & Medicaid Services. Billing and coding: use of laterality modifiers. Updated January 1, 2025. Accessed September 25, 2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56869> 7. Centers for Medicare & Medicaid Services. Place of service code set. Database (updated May 2, 2024). Accessed September 25, 2025. <https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets> 8. Noridian Healthcare Solutions. Revenue codes. Accessed September 25, 2025. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes> 9. CGS. Submitting claims when the billed amount exceeds \$99,999.99. Accessed September 25, 2025. <https://www.cgsmedicare.com/partb/pubs/news/2020/03/cope16412.html> 10. Centers for Medicare & Medicaid Services. MLN Connects Newsletter for September 11, 2025. Accessed September 25, 2025. https://www.cms.gov/training-education/medicare-learning-network/newsletter/mln-connects-newsletter-september-11-2025#_Toc208383787 11. Centers for Medicare & Medicaid Services. CMS-1500 Health Insurance Claim Form. Accessed September 25, 2025. <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf> 12. Centers for Medicare & Medicaid Services. MCPM Chapter 17 – Drugs and biologicals. Updated June 6, 2025. Accessed September 25, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf>



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